

**REMARKS**

The present invention relates to a method and a reagent for measuring alanine aminotransferase activity.

In the Office Action it appears that previous rejections under 35 U.S.C. § 112 have been withdrawn, but at page 8 of the Office Action, the Examiner has rejected claims 12 - 15, 17 - 20, and 22 - 25 under 35 U.S.C. § 112, second paragraph for indefiniteness, with respect to the recitation in claims 12 and 17

"wherein the concentration of the substance in the measuring system is a concentration *exhibiting* the lactate dehydrogenase activity",

in view of references in claims dependent thereon to a

"substance having an activity of *inhibiting* the lactate dehydrogenase activity".

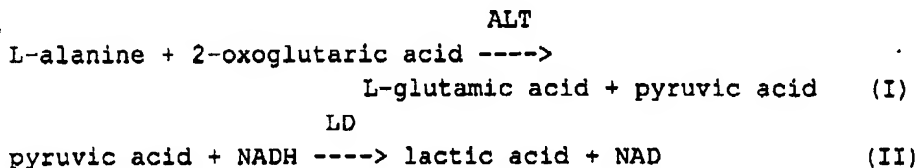
In view of the foregoing, the Examiner considered the claim recitation to be unclear.

In this connection, the word "exhibiting" in the recitation "a concentration exhibiting the lactate dehydrogenase activity" is technically accurate and correct, and not a clerical error of "inhibiting"; that is, the first quotation refers to substance being present in a concentration which exhibits the activity, and the second quotation refers to the activity of inhibiting the activity of lactate dehydrogenase. There is no inconsistency. See also the discussion below.

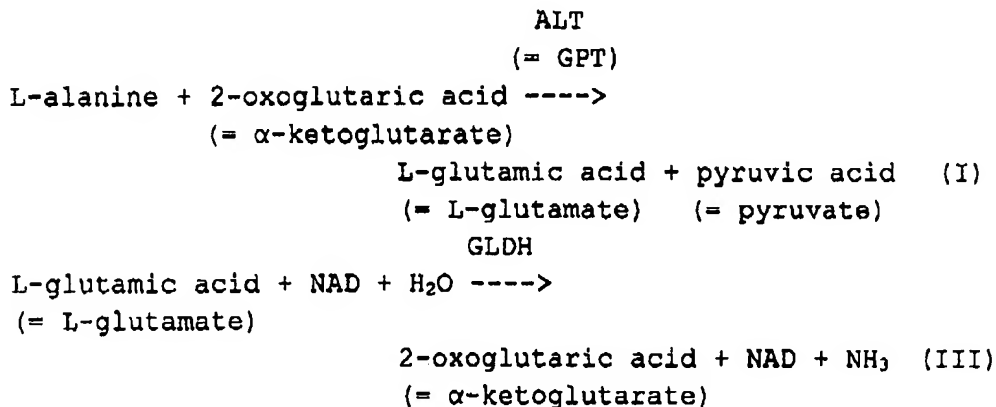
With respect to the prior art, claims 11 - 13, 15 - 20, and 21 - 25 have been rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Madappally et al, and claims 11 - 25 have been rejected under 35 U.S.C. § 103(a) over Madappally et al.

Distinctions between the present invention and the method of Madappally et al

The present invention is quite different from the method disclosed in the Madappally et al reference, with respect to a reaction system for measuring an alanine aminotransferase (ALT) activity. As previously noted, the present invention is based on the reaction formulae (I) and (II) shown below.



On the other hand, the method disclosed in the Madappally et al reference is based on the reaction formulae (I) and (III) show below.



In addition, the present invention is different from the method disclosed in the Madappally et al reference with respect to the use of "a substance having an activity of inhibiting a lactate dehydrogenase (LD) activity" (hereinafter referred to as LD inhibitor), and furthermore the concentration of the LD inhibitor.

More particularly, in the method disclosed in the Madappally et al reference, the LD inhibitor, such as oxamate or oxalate, is added to the measuring system to completely inhibit LD (see column 2, lines 47-53).

In contrast, as described on page 6, line 17 to page 7, line 4 of the present specification, in the present invention, the LD inhibitor is used at a concentration exhibiting the LD activity which does not affect the measurement of the ALT activity in the present invention. Claims 11 and 16 have been amended herein to further emphasize this distinction. In this connection, the term "exhibiting the LD activity which does not affect the measurement of the ALT activity" means that at least an LD activity capable of measuring the ALT activity remains in a sample to be analyzed. In the present invention, the LD activity is partially inhibited (i.e., not completely inhibited) by the LD inhibitor.

In view of the foregoing, it is respectfully submitted that claims 11 - 13, 15 - 20 and 21 - 25 are now even more clearly distinct and novel vis-à-vis the Madappally reference.

Unobviousness of the present invention over Madappally et al

Since the complete inhibition of the LD activity is essential in the method disclosed in the Madappally et al reference, the present invention in which the LD activity is partially inhibited by the LD inhibitor would not be easily conceivable from the disclosure of the Madappally et al reference.

Furthermore, the present invention exhibits advantageous and remarkable effects (ii-1) to (ii-3), viz.,

(ii-1) an increased reagent blank reaction (i.e., an increased initial absorbance) can be surprised,

(ii-2) accurate measured values of the ALT activity can be obtained, and

(ii-3) the reagent of the present invention exhibits an activity of stabilizing LD,

which are completely unexpected from the disclosure of the Madappally et al reference.

Therefore, the present invention in accordance with claims 11 - 25 herein is unobvious and patentable over the method disclosed in the Madappally et al reference.

In view of the above, entry of this Amendment and allowance of claims 11 - 25 of this application are now believed to be in order, and such actions are hereby earnestly solicited.

AMENDMENT UNDER 37 C.F.R. § 1.116  
U.S. Application No.: 10/507,105

Attorney Docket No.: Q83547

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the local Washington, D.C. telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.


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